K092477

510(k) SUMMARY

1. Contact Details

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OCT 29 2010

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Date Prepared: October 19, 2010

2. Device Name

Trade Name:	NeuroFAST Monitoring System, Model NF-201
Common/Usual Name:	EEG Monitor
Classification Name:	Electroencephalograph
Product Code:	OMC
Regulation Number:	21 CFR 882.1400
Device Class:	Class II
Classification Panel:	Neurology

3. Legally Marketed Predicate Device

510(k) Number	Product Code	Trade Name	Manufacturer
K082886	OLT	ZOOM-100DC	Brainscope Company, Inc.
K072382	GWQ	Model I-2000 Monitor	Infinite Biomedical Technologies

4. Description of Device

The NeuroFAST Monitoring System, Model NF-201, is an EEG monitor that records and displays electroencephalograms (EEGs) obtained from noninvasive electrodes placed on a patient's head. The acquired EEG waveforms and processed EEG variables are continuously displayed by the system for interpretation by the licensed medical professional.

The NeuroFAST Monitoring System, Model NF-201 has three main components:

- Display Module (DM-201) – processes acquired digital EEG signals, displays EEG waveforms and processed EEG variables, and archives them for later review

- Patient Module (PM-201) – acquires analog EEG signals through the Patient Cable, and converts them into digital EEG signals
- EasyPrep Sensor Kit (EK-701) – Noninvasive, disposable, single patient electrodes for acquiring the EEG signal

The NeuroFAST NF-201 system also includes the following cables:

- Patient Cable (PC-201) – connects the Patient Module to four (4) noninvasive electrodes
- USB Data Cable (DC-201) – sends acquired digital EEG signals from the Patient Module to the Display Module

5. Intended Use

The intended use of NeuroFAST Monitoring System, Model NF-201 is consistent with the classification 21 CFR 882.1400, Electroencephalograph:

> "An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head."

The NeuroFAST Monitoring System, Model NF-201 is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the head. The NeuroFAST NF-201 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and for clinical research. The NeuroFAST Monitor is to be used under the direction and interpretation of a licensed medical professional. The NeuroFAST Monitoring System, Model NF-201 does not provide any diagnostic conclusion about the patient's condition.

6. Substantial Equivalence Comparison

The technology of the NeuroFAST NF-201 device is equivalent to other EEG monitor devices. The EEG signal is acquired in analog format, digitized, processed and presented to the user for interpretation. An EasyPrep Sensor Kit is provided for the convenience of the user in applying the monitoring electrodes. The EasyPrep Sensor Kit is made of the same materials used in the manufacture of several medical sensors listed under 510(k) #781430 (refer to section 15 for addition details).

Feature	NeuroFAST Monitoring System, Model NF-201 (K092477)	ZOOM-100DC (082886)	Model I-2000 Monitor (072382)
Indications for Use	The NeuroFAST Monitor NF-201 is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the head. The NeuroFAST NF-201 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and for clinical research. The NeuroFAST Monitor is to be used under the direction and interpretation of a licensed medical professional. The NeuroFAST Monitor NF-201 does not provide any diagnostic conclusion about the patient's condition.	The ZOOM-100DC is used to measure and record the electrical activity of a patient's brain. The ZOOM-100DC is intended to monitor the state of the brain by acquisition and display of electroencephalogram (EEG) signals and by the calculation of standard quantitative EEG (qEEG) parameters.	The 1-2000 Monitor is intended to be used for measuring and recording the electrical activity of a patent's brain, obtained by placing electrodes on the head. The 1-2000 Monitor is indicated for use in monitoring the state of the brain by acquisition of electroencephalogram (EEG) signals, in research and clinical environments.
Modalities	EEG	EEG	EEG
Environment of Use	Operating room, intensive care unit, emergency room, and clinical settings where EEG monitoring is used.	Hospitals and Clinics	Hospitals and Clinics
Power Source	120 Volt 60Hz AC power	Li Ion Battery	Battery 120 Volt 60Hz AC power
System Components	Patient Module, Patient Cable, Display Module, Data Cable and EasyPrep Electrode Kit	ZOOM-100DC, External Patient Interface Cable, External Audio Cable, Compact Flash Card, Battery Charger	Table PC, Battery Powered wireless headbox, headbox charger, power conditioner
Sensing Electrodes	Silver-silver chloride disposable EEG electrodes	Standard off-the-shelf EEG electrodes	Unknown type of EEG electrodes

Feature	NeuroFAST Monitoring System, Model NF-201 (K092477)	ZOOM-100DC (082886)	Model I-2000 Monitor (072382)
Screen Display Details	Displays: 1) Raw EEG Waveforms 2) Spectral Parameters: EEG power spectrum and frequency bands, 50% 50% Median Edge Frequency (MEF), and 95% Spectral Edge Frequency (SEF)	Displays: 1) Raw EEG Waveform	Displays: 1) Raw EEG waveforms 2) Spectral Parameters: EEG power spectrum; 95% Spectral Edge Frequency (SEF)
Stored EEG data available	Yes – through removable storage	Yes – through Compact Flash card	Yes – through removable storage
EEG Channels/ Montage	2 bilateral frontal channels viewed concurrently	Up to 5 channels viewed concurrently 8 single-ended channels corresponding to 8 electrodes placed anywhere on the head, including but not limited to, all locations defined by the International 10/20 system. (5 different channels can be viewed concurrently)	2 channels
Real Time EEG Display	Yes	Yes	Yes
Processed EEG Bandwidth	User Selectable Low Filter: 0.125 or 0.5 Hz High Filter: 30 or 70 Hz	0.5-50 Hz	Unknown
Automatic Artifacting	Yes	Yes	Unknown
Amplifier Common Mode Rejection Ration (CMRR)	≥100 dB	≥ 100 dB	Unknown
Amplifier Input Impedance	≥50 Meg Ohm	≥ 100 Meg Ohms	Unknown
Electrode Impedance Test	Yes Continuous and on demand by the user	Yes	Yes

Feature	NeuroFAST Monitoring System, Model NF-201 (K092477)	ZOOM-100DC (082886)	Model I-2000 Monitor (072382)
Derived / Processed EEG Measures	Power spectrum parameters derived from FFT: 1) Power spectrum displayed as Density Spectral Array (DSA) 2) 95% Spectral Edge Frequency (SEF) 3) Median Edge Frequency (MEF) 4) Spectral Powers in EEG frequency bands traditionally used to quantify EEG signals (α, β1, β2, δ, θ and γ)	Power spectrum parameters derived from FFT: 1) Absolute Power a. Monopolar Power b. Bipolar Power 2) Relative Power a. Relative Monopolar Power b. Relative Biopolar Power 3) Mean frequency variables (univariate and multivariate) a. Monopolar Mean Frequency b. Biopolar Mean Frequency 4) Coherence a. Monopolar Coherence b. Bipolar Coherence 5) Asymmetry a. Monopolar Asymmetry b. Bipolar Asymmetry	Power spectrum parameters derived from FFT: 1) Power spectrum displayed as a line graph for each of the four frequency bands traditionally used to quantify EEG signals [Delta (0-4 Hz), Theta (4-8Hz), Alpha (8-13Hz) and Beta (13-30 Hz)] 2) 95% spectral edge frequency (SEF)
Contains patient isolation	Yes – Patient module (analog-to digital converter) provides 6kV electrical isolation of the patient from the monitor	Battery powered, thus no connection between patient and mains	Yes – Wireless Bluetooth communication provides electrical isolation of the patient from the monitor
Display Screen	Yes – High-resolution, color, graphical user interface and touch screen	Yes	Yes – Graphical user interface and touch screen tablet PC
Event Markers	Yes, user selectable	Unknown	Yes

7. Non-clinical Testing

Laboratory testing, performed on identical hardware to the NeuroFAST subject of this submission, demonstrated that the NeuroFAST Monitoring System, Model NF-201 meets its design and functional requirements, including IFCN Guidelines for electroencephalographs. Actual device functions and features were evaluated against the device specifications and in all instances the NeuroFAST NF-201 performed as expected and no unexpected behavior was observed. The device will meet the requirements of UL medical electrical equipment standards for safety and the IEC particular standard for electroencephalographs.

To ensure safety, the NeuroFAST Monitoring System, Model NF-201 will comply with all applicable requirements of IEC60601-1 and IEC60601-1-4, and will also comply

with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

To ensure electromagnetic compatibility, the NeuroFAST NF-201 will comply with all applicable requirements of IEC60601-1-2, and will also comply with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

8. Clinical Testing

The NeuroFAST NF-201 device is an electroencephalographic device comprised of hardware that has been bench tested to assess safety and effectiveness and to establish substantial equivalence with the predicate devices. We believe further clinical data is not required to demonstrate performance for the NeuroFAST NF-201 for the indication for use subject to this submission.

9. Conclusion

The NeuroFAST NF-201, when compared to its predicate devices, has the same intended use and similar technological characteristics and principles of operation. The nonclinical tests demonstrate that the device is safe, as effective, and performs at least as safely and effectively as the legally marketed devices. Thus, in indications, intended use and technology, the NeuroFAST NF-201 is substantially equivalent to the predicated devices. Minor technological difference as documented in the Substantial Equivalence Comparison table above, raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeuroWave Systems, Inc.
c/o Ms. Tracie Capozzio
Quality Assurance and Regulatory Compliance
2490 Lee Blvd., Suite 300
Cleveland Heights, Ohio 44118

OCT 29 2010

Re: K092477
Trade/Device Name: NeuroWave NeuroFAST Monitoring System, Model NF-201
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph (EEG)
Regulatory Class: Class II
Product Code: OMC
Dated: October 19, 2010
Received: October 20, 2010

Dear Ms. Capozzio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092477

OCT 29 2010

Device Name: NeuroFAST Monitoring System, Model NF-201

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092477